



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Denver District Office  
Building 20 – Denver Federal Center  
P.O. Box 25087  
Denver, Colorado 80225-0087  
TELEPHONE: 303-236-3000

January 24, 2000

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

Mr. Carlos Villapando  
Owner / Manager  
Rockhill Dairy, L.L.C.  
104 Ojibwa Road  
Dexter, NM 88230

Ref. #. –DEN- 00-12

Dear Mr. Villapando,

Food and Drug Investigator Margaret M. Annes conducted an investigation of your dairy farm operations located at 104 Ojibwa Road, Dexter, NM, on December 3, 1999. That inspection confirmed that you offered animals for sale for slaughter as food, in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, you sold two cows on different occasions in April and June 1999 at [redacted] which were subsequently slaughtered for food and found to contain illegal levels of drug residues by USDA testing. These incidents were recorded under USDA case # 99-0315-NM:

**April 28, 1999** USDA analysis of tissue samples collected from your animal (USDA Sample #352667) identified the presence of a Penicillin residue of [redacted] ppm in the kidney. A tolerance of 0.05 has been established for residues of Penicillin in the edible tissues of cattle in Title 21 Code of Federal Regulations, Part 556.510 (21 CFR 556.510).

**June 23, 1999** USDA analysis of tissue samples collected from your animal (USDA Sample #400002) identified the presence of a Gentamicin residue of [redacted] ppm in the kidney. No tolerance has been established for residues of Gentamicin in the edible tissues of dairy cattle in 21 CFR 556.300.

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Our investigation revealed the use of BS-Clear (Gentamicin Sulfate, Dexamethazone, and Neomycin) or Agri-cillin to treat these cows. The presence of Gentamicin or Penicillin drug at the levels found in edible tissues from this animal cause the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

BS-Clear was used in an extra-label manner. There are limitations and conditions established for extra-label drug use or intended extra-label drug use in animals (21 CFR 530 – Extra-label Drug Use in Animals), a copy of which is enclosed with this letter. You should review all your drug use practices to assure you are compliant with 21 CFR 530.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues may enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you or under your direction have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues from edible tissues. The food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the Act.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended as an all-inclusive list of violations. As a dairy farm operator and owner/seller of medicated animals for food use, you are responsible for assuring that your overall operation and the products you distribute are in compliance with the law. You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies. To avoid future illegal residue violations you should take precautions such as:

- 1) Implement a system to withhold a medicated animal from slaughter for food for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal, then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.
- 2) Implement a system for medical treatment records that include: drug used, treatment period, who administered the drug, amount administered, appropriate withdrawal period and the animal's identification.

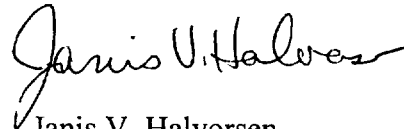
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- 3) Implement a system for drug use, including extra-label use, which is only authorized by a veterinarian, and storage to prevent inappropriate access and use.

You should notify this office in writing within 15 working days of the receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Betty Kay Baxter, Acting Compliance Officer, at the above address. If you have questions regarding this letter you may contact Ms. Baxter at (303) 236-3084.

Sincerely,



Janis V. Halvorsen  
Acting District Director

Enclosure:  
As Stated

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